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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/358,141 07/20/99 SAMPSON

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HM22/0130

EXAMINER

SCHMIDT, M

ART UNIT

PAPER NUMBER

1635

DATE MAILED:

01/30/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/358,141

Applicant(s)

SAMPSON, JEFFREY R.

Examiner

Mary Schmidt

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1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2010
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-18 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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### **DETAILED ACTION**

1. The following Action replaces the restriction requirement mailed 10/4/00 of pending claims 1-18. Therefore, a new election is required as set forth below.

#### ***Election/Restriction***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-9, drawn to methods of synthesizing an unstructured nucleic acid, classifiable in class 435, subclass 91.1.
  - II. Claim 10, drawn to methods of using an unstructured nucleic acid made by the process of claim 1, classifiable in class 435, subclass 6.
  - III. Claims 11-18, drawn to unstructured nucleic acid compositions, classifiable in class 536, subclass 23.1.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the unstructured nucleic acids as broadly defined read on any nucleic acid molecules having synthetic modifications. Such synthetic nucleic acids are made by many different methods in the art, including chemical reactions which do not use an enzyme for incorporation of the synthetic precursors as in the methods of Invention I.

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Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different method steps, modes of operation. Group I is drawn to a method of making the unstructured nucleic acids and Group II is drawn to a method of using the unstructured nucleic acids.

4. Should Group I be elected, the following restriction to one of Groups IA-IE is also required for claims 1-9 as follows:

IA. Claims 1-9, drawn to methods of synthesizing an unstructured nucleic acid using an RNA polymerase.

IB. Claims 1-9, drawn to methods of synthesizing an unstructured nucleic acid using a DNA polymerase.

IC. Claims 1-9, drawn to methods of synthesizing an unstructured nucleic acid using a reverse transcriptase.

ID. Claims 1-9, drawn to methods of synthesizing an unstructured nucleic acid using a ribozyme.

IE. Claims 1-9, drawn to methods of synthesizing an unstructured nucleic acid using a self-replicating RNA molecule.

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Inventions IA-IE are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation depending on the type of enzyme used in the methods of synthesis of the unstructured nucleic acids. Specifically, DNA polymerases, RNA polymerases, reverse transcriptase, ribozymes and self-replicating RNA molecules each function by a different mechanism known in the art and thus would function differently in their capacity to make unstructured nucleic acids as claimed.

5. Further, should Group II, claim 10, be elected, the following restriction to one of Groups IA-IC is also required for claims 1-9 as follows:

IIA. Claim 10, drawn to methods of using an unstructured nucleic acid in a ligase assay.

IIB. Claim 10, drawn to methods of using an unstructured nucleic acid in a polymerase extension assay.

IIC. Claim 10, drawn to methods of using an unstructured nucleic acid in a nucleic acid array.

Inventions IIA-IIC are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different

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functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. Specifically, the method steps involved in a ligase assay, polymerase extension assay or nucleic acid array widely differ in the art and as such require scientific considerations considered patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their divergent classification and recognized divergent subject matter, and the search required for each of Group I, II or III, and further for sub-groups IA-IE and sub-groups IIA-IIC is not required for the other Groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mary M. Schmidt*, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *George Elliott, Ph.D.* may be reached at (703) 308-4003.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

M. M. Schmidt  
January 29, 2001



REMY YUCEL, PH.D  
PRIMARY EXAMINER